UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,731	06/23/2003	Joseph Raymond Faryniarz	J6829(C)	7564

201 7590 07/13/2006

UNILEVER INTELLECTUAL PROPERTY GROUP
700 SYLVAN AVENUE,
BLDG C2 SOUTH
ENGLEWOOD CLIFFS, NJ 07632-3100

EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/601,731
Filing Date: June 23, 2003
Appellant(s): FARYNIARZ ET AL.

Milton Honig
Registration Number 28,617
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 26, 2006 appealing from the Office action mailed February 27, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

The examiner notes that appellant has filed appeal briefs in US Patent Application 10/347982; 10374300; 10/601856, and 10/767679. Although these copending applications are not related to this application as continuations, the copending applications are directed to compositions comprising malonic acid salts present as half neutralized or fully neutralized acids in specific molar ratios.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,641,495	JOKURA et al	6-1997
WO 00/61107	BEERSE et al	10-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A) Claims 1 and 3-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jokura et al (5,641,495).

Jokura teaches a skin cosmetic containing having an excellent moisturizing effect comprising: (A) a ceramide or a pseudoceramide; (B) a dicarboxylic acid; and (C) a salt of a dicarboxylic acid. See abstract. The composition is used for treating dry skin in the winter and applicable to the skin around the eyes to prevent crow's feet, i.e. fine lines around the eyes. See column 5, lines 35-39. The composition softens the keratinous layer. See column 1, lines 7-20.

Jokura teaches examples of the dicarboxylic acid (B) include **malonic** acid, succinic acid, fumaric acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid. The dicarboxylic acid salt (C) include alkali metal (for example, sodium, potassium) salts; alkali earth metal (for example, calcium, magnesium) salts; **alkanolamine** (for example, triethanolamine) salts; basic amino acid (for example, lysine, arginine) salts and **ammonium** salts. Note that the term amine encompasses Jokura's alkanolamines, arginine, lysine, and ammonium. These dicarboxylic acid salts may be added in the form of a salt at the step of the preparation of the skin cosmetic of the present invention. Alternatively, an acid may be added followed by the addition of an alkali (sodium hydroxide, etc.) to thereby form the aimed salt via

neutralization in the system. To achieve a sufficient moisturizing effect while avoiding excessive irritation, it is preferable that the content of components (B) and (C), falls within a range of from 0.01 to 20% by weight, still preferably from 0.05 to 15% by weight and preferably 0.01 to 10% by weight. To achieve a sufficient moisturizing effect while avoiding irritation due to the acid, it is preferable that the molar ratio of the components (B) to (C) falls within a range of from 1/9 to 9/1, still preferably from 2/8 to 8/2. See column 3, lines 30-60. Furthermore, Jokura teaches regulating the pH value of the skin cosmetic, which contains the components (B) and (C), to pH 3 to 10, still preferably to pH 3 to 9, to avoid the irritation observed at a pH value less than 3 or exceeding 10. See column 3, lines 60-65. The examples utilize a pH of 4.1. When oily substances are used as the carrier, the content of the oily substance in is a range from 0.01 to 50% by weight. See column 4, lines 14-16. When water, ethanol and/or water-soluble polyhydric alcohols are employed as the carrier, the content is preferably from 0.01 to 95% by weight. See column 4, lines 30-35.

Jokura et al do not specify the acid to salt molar ratio of component (C) (the degree of neutralization).

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Jokura et al and manipulate the acid to salt ratio of component (C). One would have been motivated to manipulate the ratio of the salt to acid since partial or full neutralization of the acid by the salt (salt acts as the neutralizing agent) adjusts the pH of the composition. Thus, one would have been motivated to utilize the desired acid: salt ratio depending on the desired pH of the composition. For instance, Jokura teaches the importance of avoiding skin irritation due to the acid; thus the pH must be above 3 and below 10

(see column 3, lines 30-65). Therefore, a skilled artisan would have been motivated to use a sufficient amount of salt to either partially or fully neutralize the acid in the composition to render a pH that does not irritant the skin wherein using equimolar amounts of the salt and acid (full neutralization) would contribute to the overall increase of the pH of the composition whereas partial neutralization of the acid would contribute to the overall decrease of the pH of the composition since the compound is in a slightly acidic form. Additionally, it should be noted that generally differences in concentrations, such as the instantly claimed molar ratio of acid to salt, do not support the patentability of subject matter that is encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regard to the recitation of "wherein the composition exhibits a Flexibility Value greater than 1 in the Porcine Skin Test", it is the examiner's position that Jokura's composition will implicitly have a Flexibility value of greater than 1 since the instant disclosure on page 5 states that malonate salts impart the flexibility value to the composition and they impart a value of at least 1.1. Secondly, the prior art teaches the same malonic acid salt in the same weight percent. Therefore, the prior art's composition and the instant composition, which recites open-claim language, are identical, it is the examiner's position that they will exhibit the same property, i.e. the instant flexibility value.

B) Claims 1, 3-4, 6-9, 11-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/61107 to Beerse et al.

Beerse discloses an antimicrobial wipe that is impregnated with an antimicrobial cleansing composition. See abstract. Specifically example 14 discloses a composition comprising

3.20% sodium malonate, additional components, and the balance water (84.03% of the carrier). The wipe is suitable for application to the human skin to remove oil and dirt. Further, the composition is useful for treatment of acne and improvement of skin appearance. The improvement includes providing a smoother and more even appearance of the skin and regulating the signs of aging (wrinkles, fine lines, sagging, loss of skin's firmness, etc). See page 4, lines 25-36 and in particular page 5, lines 1-30. Beerse teaches the proton donating agent selected from acids such as glycolic, citric, malonic, etc. in an amount of 0.1-10%, preferably 0.5-8% is either directly added or added in its conjugated base of the desired acid and the acid remains at least in a partially undissociated form. Further, Beerse teaches that the pH of the invention is critical since the benefits of the invention lie in the undissociated acid form the proton donating agent remain on the skin and the pH should be 3-6 and preferably 3-5, wherein the pH is adjusted accordingly. Beerse teaches the manipulation of the pH based on the acid and base. See page 18.

Beerse does not specify the acid to salt molar ratio of component (C) (the degree of neutralization).

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Beerse et al and manipulate the acid to salt ratio of component of the malonate salt, i.e. sodium malonate. One would have been motivated to manipulate the ratio of the salt to acid since partial or full neutralization of the acid by the salt (salt acts as the neutralizing agent) adjusts the pH of the composition. Thus, one would have been motivated to utilize the desired acid: salt ratio depending on the desired pH of the composition. For instance, Beers teaches the importance of a pH between 3 and 6 and

buffering it accordingly. Thus, depending on the pH desired, a skilled artisan would have been motivated to use a sufficient amount of salt to either partially or fully neutralize the acid in the composition to render the desired pH, wherein using equimolar amounts of the salt and acid (full neutralization) would contribute to the overall increase of the pH of the composition whereas partial neutralization of the acid would contribute to the overall decrease of the pH of the composition since the compound is in a slightly acidic form. Additionally, it should be noted that generally differences in concentrations, such as the instantly claimed molar ratio of acid to salt, do not support the patentability of subject matter that is encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regard to the recitation of "wherein the composition exhibits a Flexibility Value greater than 1 in the Porcine Skin Test", it is the examiner's position that Beerse's composition will implicitly have a Flexibility value of greater than 1 since the instant disclosure on page 5 states that malonate salts impart the flexibility value to the composition and they impart a value of at least 1.1. Secondly, the prior art teaches the same malonic acid salt in the same weight percent. Therefore, the prior art's composition and the instant composition, which recites open-claim language, are identical, it is the examiner's position that they will exhibit the same property, i.e. the instant flexibility value.

(10) Response to Argument

A) Claims 1 and 3-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jokura et al (5,641,495).

Appellant argues that Jokura does not exemplify malonic acid and only mentions it once. Appellant argues that a variety of cationic salts are mentioned and although amines are present, they are not predominant. Appellant argues that the examples do not utilize amines as the neutralizing agent of the acids. Appellant argues that succinic acid and sodium succinate are exemplified and thus the prior art teaches away from a half neutralized acid salt as claimed.

Firstly, the examiner points out that a reference need not exemplify an embodiment to anticipate or render an invention obvious. The examiner points out that although malonic acid is not exemplified, malonic acid is taught and it does not appear in a "laundry list" as argued by appellant. The acids taught by Jokura are sufficiently limited (malonic acid, succinic acid, fumaric acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid). With regard to the salt, Jokura teaches the salt of the dicarboxylic acid may be 1) alkali metal (for example, sodium, potassium) salts; 2) alkali earth metal (for example, calcium, magnesium) salts; 3) alkanolamine (for example, triethanolamine) salts; 4) basic amino acid (for example, lysine, arginine) salts and 5) ammonium salts. Note that the term amine encompasses Jokura's alkanolamines, basic amino acids (lysine and arginine), and ammonium. Therefore, it is the examiner's position that although Jokura does not exemplify malonic acid or the amine salt, this does not constitute a teaching away since clearly the prior art clearly discloses the malonic acid and the amine salt. The examiner respectfully submits that disclosed examples and preferred embodiments do not constitute a teaching away form the broader disclosure or nonpreferred embodiment as set forth in *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Thus, the fact that Jokura does not exemplify all acids and its salt forms, does not constitute a teaching away from the broader disclosure.

Secondly with regard to the neutralization ratio, although Jokura teaches neutralization of the acid with a salt, the examiner notes that Jokura does not specify the molar ratio of the partially to fully neutralized acid. However, it is the examiner's position that the lack of exemplification of the instant ratio is not equivalent to "a teaching away" or a lack of obviousness as asserted by appellant. Hence, the premise of the obviousness rejection is based the examiner's position that the manipulation of the neutralization ratio is prima facie obvious, which will be discussed in detail below.

Appellant argues that Jokura et al teach a having a combination of the unneutralized acid (free acid) and a partially neutralized acid. Appellant argues that "the free acid can only co-exist with a partially neutralized salt because of pKa considerations" and all three species (free acid, partially neutralized acid, and neutralized acid) cannot coexist.

As acknowledged by appellant, neutralization of an acid is based on pH consideration (wherein the existence of partially neutralized acid to fully neutralized acid provides a desired pH,; however the examiner respectfully disagrees that the free acid, partially neutralized acid, and a fully neutralized salt cannot coexist.

The acid/base equilibrium equation is known to one of ordinary skill in the art and is as follows for a dicarboxylic acid, such as malonic acid, in an aqueous solution:

$$HO_2CCH_2CO_2H \xrightarrow{K_{a1}} HO_2CCH_2CO_2^- + H^+ \xrightarrow{K_{a2}} O_2CCH_2CO_2^{2-} + 2H^+$$

formula (I) formula (II)

K_{a1} and K_{a2} are the equilibrium constant for each neutralization reaction (acid equilibrium) and formula (I) and (II) represent the instant formulas as recited in the claims. The

X counter ion is not included in the equation. This is standard convention to those of ordinary skill in the art since the counter ions are not reactants or products that participate in the acid-base reaction. Instant formula (I) (the partially neutralized salt form) is equivalent in solution to the singly deprotonated formula (I) shown in the above equation (i.e. one acid moiety has been "neutralized), and instant formula (II) (the fully neutralized salt) is equivalent in solution to the doubly deprotonated formula (II) shown in equation above (i.e. two acid moieties having been "neutralized").

The free acid, partially neutralized acid, and fully neutralized acid, exist in solution in equilibrium with one another, with the concentration of the different forms being governed by the individual K_a of each neutralization reaction. For example, as known to those of ordinary skill in the art, the equilibrium constant Ka_2 for the ratio of the concentration of the "fully neutralized" products (formula II) to concentration of the "partially neutralized" reactants (formula II) is expressed as:

$$K_{a2} = \text{[concentration of products]/ [concentration of reactants]}$$

$$= 2[H^+]\,[O_2CCH_2CO_2^{2-}]/\,[H^+]\,[HO_2CCH_2CO_2^-]$$

$$= [H^+]\,[O_2CCH_2CO_2^{2-}]/\,[HO_2CCH_2CO_2^-]$$

The equilibrium constant is a "constant" for a given reaction; thus the concentration of products and reactants will shift when the concentration of any of the products or reactants are changed in solution, in order to achieve the equilibrium K_a value. This concept is known as LeChatelier's Principle and is found in high school and college chemistry books. Adding reactants to the solution creates a ratio of [products]/[reactants] that is lower than the K_a at equilibrium; thus the reaction will proceed in the forward direction to form more product, until a

ratio of [products]/[reactants] that equals the equilibrium constant K_a is achieved. Similarly, increasing the concentration of any of the products, such as (H+) or $[O_2CCH_2CO_2^{2-}]$ creates a ratio of [products]/[reactants] that is too high, and causes the (reaction to proceed in reverse to form more reactants, until the equilibrium ratio K_a of the products to the reactants is achieved. Thus, adding or removing amounts of the product (H+) to the solution results in the formation of more reactants, i.e. the partially neutralized salt, and effectively changes the ratio of partially to fully neutralized acid forms.

The effect of changes in the concentration of $[H^+]$ on the equilibrium amounts of the products and reactant can also be seen by rearranging equation 2:

$$K_{a2}/[H^+] = [O_2CCH_2CO_2^{2-}]/[HO_2CCH_2CO_2^-]$$

The right hand side of the equation is equivalent to the ratio of fully neutralized: partially neutralized acid, the inverse of the ratio as is recited in claim 1 and 6. Thus, as K_{a2} is a constant for the given acid, malonic acid, the ratio of partially neutralized acid to fully neutralized acid will be dependent upon the concentration of H^+ in solution. In other words, the ratio of partially neutralized to fully neutralized acid is governed by the pH of the solution ($pH = - \log[H^+]$). That is, solutions having the same pH should have the same or similar ratios of partially neutralized to fully neutralized salts.

The examiner points out that although the instant specification does not specify a pH, paragraph [0006] of the instant specification that discloses a low pH causes undue irritation. It is conventional knowledge in the cosmetic art that extremely low pH (acidic) or extremely high (basic) irritate the skin; this is evidenced by Jokura's teaching that a pH value of below 3 or exceeding 10 causes skin irritation. Further, on column 5, lines 35-38 Jokura characterizes the

composition as, "being less irritative and having an excellent moisturizing effect". Jokura teaches a pH range of 3 to 10, preferably 3 to 9, and exemplifies a pH of 4.1 This pH range encompasses the generally accepted pH of 7 (neutral pH) that is considered nonirritating and suitable for cosmetic products. Although appellant does not specify a pH, the composition is directed to a "cosmetic composition" and the method is directed to applying to the skin; hence the composition must have a pH that is suitable for application to the skin. Thus, absent evidence to the contrary, the pH of the inventive cosmetic must have a pH range of 7; or in a range that is close to 7; or have a pH range that falls within the prior art's pH range of 3 to 9, i.e. a range that does not have extreme pH to irritate the skin. It is the examiner's position that the prior art and the instant composition would have close (to render it obvious) if not an overlapping pH. Therefore, the ratio of partial to neutralized acid would be similar. Moreover, it respectfully pointed out that is within the skill of the art to manipulate this ratio to render the desired and optimal pH. Jokura cautions that a pH value of below 3 or exceeding 10 causes skin irritation and Jokura teaches varying the free acid to acid salt to manipulate the pH within this range. Thus, a skilled artisan would have been motivated to manipulate this ratio of free acid to the acid salt as taught by Jokura et al, which would thereby simultaneously manipulate the ratio of the partially neutralized to fully neutralized acid to render a pH that is non-irritating to the skin. Thus although the prior art does not expressly disclose the manipulation of the partial to fully neutral acid salt itself, this step is *implicit* when the pH of the composition is adjusted. Therefore, the examiner respectfully submits that differences in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as

concentration is critical as set forth in *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In instant case, appellant has not shown the unexpectedness of the instant ratio.

Appellant argues that experiments noted in the instant specification demonstrate that malonate salts are much better than glycolate or succinate salts with respect to improving skin flexibility. Appellant argues that a skilled artisan would not have been motivated to select malonate over succinate especially in view of appellant's results demonstrated in example 9.

Firstly, although the results on page 9 of the instant specification are noted, the examiner points out that the obviousness rejection is based on manipulation of the neutralization ratio and not the use of malonic acid versus glycolic acid since it is the examiner's position that Jokura envisages the use of malonic acid as discussed above. Thus, the clinical data in the specification is considered to be unpersuasive since appellant's clinical studies do not rebut the premise of rejection based on the manipulation of the neutralization ratio. Secondly, assuming arguendo that the use of malonic acid is not immediately envisaged and a skilled artisan would have to specifically pick malonic acid, the examiner notes the following about the unexpected results the applicant relies on. Example 9 utilizes two specific malonic acid salts, i.e. ammonium and dimethylethanolammonium salt, and the instant independent claims are broadly directed to the genus "salts" wherein the examples utilizes amine salts specifically. It is unclear if the same flexibility is imparted by the entire genus since the term salt is extremely broad and amine salts are known to have specific properties themselves. Therefore, the claims are not commensurate with the "unexpected results". Moreover, the examiner notes that example 9 does not set forth the concentration that each acid salt is. For instance, if applicant utilized a weight percent of 8% of the malonate salt and compared it with a 4% succinate salt, the results may be influenced by

the concentration rather than the type of acid salt utilized. Lastly, the examiner notes that example 9 compares glycolic acid and succinic acid that has been neutralized with ammonium salt with malonic acid which has been neutralized with dimethylethanolammonium salt. The examiner notes that the non-patent literature Dermatology Time, February 2002 submitted by appellant in the information disclosure statement of 1/23/04, teaches dimethylethanolammonium itself improves wrinkles. Thus, a multitude of variables are present and it cannot be determined if the unexpected result is due to the type of acid (malonic acid versus glycolic and succinic acid) used as argued by appellant or the results are due to the other variables including the concentration of the acid salt used and the type of salt used in neutralizing the acid. Thus, it is the examiner's position that appellant's data cannot clearly establish the unexpectedness of using instant malonic acid versus other acids.

B) Claims 1, 3-4, 6-9, 11-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/61107 to Beerse et al.

Appellant acknowledges Beerse teaches a composition comprising sodium malonate and malonic acid. However, appellant argues that Beerse only teaches one malonate salt and it is unclear if the salt is partially neutralized or fully neutralized. Appellant that Beerse does not render the instant invention obvious since Beerse only utilizes malonic acid as a proton-donating agent and thus a skilled artisan would not have been motivated to utilize malonic acid for the instantly claimed purpose of controlling the signs of aging and improving skin softness.

Firstly, the examiner respectfully points out that the fact that applicant has recognized another advantage, i.e. the malonic acid salt also functions to treat aging, which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when

the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In instant case, appellant is claiming a product comprising a malonate salt and the prior art teaches a composition comprising sodium malonate. The fact that Beerse may use the malonic acid salt for a different purpose than the applicant is irrelevant since the prior art composition comprises the claimed element. Secondly, the examiner points to page 5 wherein Beerse clearly teaches the composition is useful in regulating signs of aging including lines and wrinkles. Thus, Beerse teaches a composition comprising the claimed element, malonic acid, for the same purpose.

Appellant argues that the sodium malonate in example 14 of Beerse must be a half neutralized sodium salt since Beerse requires a free acid. Appellant argues that "the free acid can only co-exist with a partially neutralized salt because of pKa considerations" and all three species (free acid, partially neutralized acid, and neutralized acid) cannot coexist.

As noted by appellant the neutralization of an acid is based on pH consideration wherein the existence of partially neutralized acid to fully neutralized acid provides a desired pH,; however the examiner respectfully disagrees that the free acid, partially neutralized acid, and a fully neutralized salt cannot coexist.

The acid/base equilibrium equation is known to one of ordinary skill in the art and is as follows for a dicarboxylic acid, such as malonic acid, in an aqueous solution:

$$\underset{\text{formula (I)}}{HO_2CCH_2CO_2H} \xrightarrow{K_{a1}} \underset{\text{formula (II)}}{HO_2CCH_2CO_2^-} + H^+ \xrightarrow{K_{a2}} O_2CCH_2CO_2^{2-} + 2H^+$$

K_{a1} and K_{a2} are the equilibrium constant for each neutralization reaction (acid equilibrium) and formula (I) and (II) represent the instant formulas as recited in the claims. The X counter ion is not included in the equation. This is standard convention to those of ordinary skill in the art since the counter ions are not reactants or products that participate in the acid-base reaction. Instant formula (I) (the partially neutralized salt form) is equivalent in solution to the singly deprotonated formula (I) shown in the above equation (i.e. one acid moiety has been "neutralized), and instant formula (II) (the fully neutralized salt) is equivalent in solution to the doubly deprotonated formula (II) shown in equation above (i.e. two acid moieties having been "neutralized").

The free acid, partially neutralized acid, and fully neutralized acid, exist in solution in equilibrium with one another, with the concentration of the different forms being governed by the individual K_a of each neutralization reaction. For example, as known to those of ordinary skill in the art, the equilibrium constant Ka_2 for the ratio of the concentration of the "fully neutralized" products (formula II) to concentration of the "partially neutralized" reactants (formula II) is expressed as:

$$K_{a2} = [\text{concentration of products}]/ [\text{concentration of reactants}]$$

$$= 2[H^+] [O_2CCH_2CO_2^{2-}]/ [H^+] [HO_2CCH_2CO_2^-]$$

$$= [H^+] [O_2CCH_2CO_2^{2-}]/ [HO_2CCH_2CO_2^-]$$

The equilibrium constant is a "constant" for a given reaction; thus the concentration of products and reactants will shift when the concentration of any of the products or reactants are changed in solution, in order to achieve the equilibrium K_a value. This concept is known as LeChatelier's Principle and is found in high school and college chemistry books. Adding

reactants to the solution creates a ratio of [products]/[reactants] that is lower than the K_a at equilibrium; thus the reaction will proceed in the forward direction to form more product, until a ratio of [products]/[reactants] that equals the equilibrium constant K_a is achieved. Similarly, increasing the concentration of any of the products, such as (H+) or $[O_2CCH_2CO_2^{2-}]$ creates a ratio of [products]/[reactants] that is too high, and causes the (reaction to proceed in reverse to form more reactants, until the equilibrium ratio K_a of the products to the reactants is achieved. Thus, adding or removing amounts of the product (H+) to the solution results in the formation of more reactants, i.e. the partially neutralized salt, and effectively changes the ratio of partially to fully neutralized acid forms.

The effect of changes in the concentration of $[H^+]$ on the equilibrium amounts of the products and reactant can also be seen by rearranging equation 2:

$$K_{a2}/[H^+] = [O_2CCH_2CO_2^{2-}]/[HO_2CCH_2CO_2^-]$$

The right hand side of the equation is equivalent to the ratio of fully neutralized: partially neutralized acid, the inverse of the ratio as is recited in claim 1 and 6. Thus, as K_{a2} is a constant for the given acid, malonic acid, the ratio of partially neutralized acid to fully neutralized acid will be dependent upon the concentration of H^+ in solution. In other words, the ratio of partially neutralized to fully neutralized acid is governed by the pH of the solution ($pH = - \log[H^+]$). That is, solutions having the same pH should have the same or similar ratios of partially neutralized to fully neutralized salts. The examiner points out that although the instant specification does not specify a pH, the specification on paragraph [0006] teaches that a low pH causes undue irritation. It is conventional knowledge in the cosmetic art that extremely low pH (acidic) or extremely high (basic) irritate the skin. Although appellant does not specify a pH, the

composition is directed to a "cosmetic composition" and the method is directed to applying to the skin for controlling the signs of aging; hence the composition must have a pH that is suitable for application to the skin. Thus, it is the examiner's position that since Beerse teaches a composition for the same purpose with a pH of 3 to 6, preferably 3 to 5, and preferably 3.5-4.5 on page 19, lines 1-2, the prior art and the instant composition would have close (to render it obvious) if not an overlapping pH in order to have a pH that is suitable for application. Therefore, the ratio of partial to neutralized acid would be similar. Moreover, it respectfully pointed out that is within the skill of the art to manipulate this ratio to render the desired and optimal pH. Beerse teaches on page 18 that the composition must have a pH between 3 to 6 and this achieved with a an acid such as malonic acid. Therefore, a skilled artisan would have been motivated to manipulate the ratio of free acid to the acid salt as taught (which would thereby simultaneously manipulate the ratio of the partially neutralized to fully neutralized acid) to render a pH on the scale of 3 to 6. Thus although the prior art does not expressly disclose the manipulation of the partial to fully neutral acid salt itself, this step is *implicit* when the pH of the composition is adjusted. Therefore, the examiner respectfully submits that differences in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical as set forth in *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In instant case, appellant has not shown the unexpectedness of the instant ratio.

Appellant argues that the instant specification provides the unexpectedness of the malonate salts versus succinate salts. Appellant argues that the instant malonate salt mixture provides a better flexibility value. Appellant argues that the prior art does not comprises a

mixture of partially neutralized acid salt to fully neutralize acid salt and therefore the prior art's composition does not have the instant flexibility value.

Firstly, the examiner respectfully points out that "unexpected results' are insufficient to overcome the instant rejection since the rejection is based on the manipulation of the neutralization ratio. The examiner submits that the rejection is not based on the use of malonate salts versus succinate salts and this argument is rendered moot by the prior art's example 14 which clearly teaches malonate salts.

However, the examiner notes the following with regard to the "unexpected results" presented by appellant. The instant claims are broadly directed to a malonic acid salt whereas the "unexpected results" in the specification utilize two specific amine salts i.e. ammonium and dimethylethanolammonium salt. It is unclear if the same flexibility is imparted by the entire genus since the term salt is extremely broad and amine salts are known to have specific properties themselves. Therefore, the claims are not commensurate with the "unexpected results". Moreover, the examiner notes that example 9 does not set forth the concentration that each acid salt is. For instance, if applicant utilized a weight percent of 8% of the malonate salt and compared it with a 4% succinate salt, the results may be influenced by the concentration rather than the type of acid salt utilized. Lastly, the examiner notes that example 9 compares glycolic acid and succinic acid that has been neutralized with ammonium salt with malonic acid which has been neutralized with dimethylethanolammonium salt. The examiner notes that the non-patent literature Dermatology Time, February 2002 submitted by appellant in the information disclosure statement of 1/23/04, teaches dimethylethanolammonium itself improves wrinkles. Thus, a multitude of variables are present and it cannot be determined if the

unexpected result is due to the type of acid (malonic acid versus glycolic and succinic acid) used as argued by appellant or the results are due to the other variables including the concentration of the acid salt used and the type of salt used in neutralizing the acid. Thus, it is the examiner's position that appellant's data cannot clearly establish the unexpectedness of using instant malonic acid versus other acids.

With regard to the flexibility value, although the appellant argues that the instant porcine value is only accomplished using a mixture of salt species, the examiner notes the instant specification:

> "A feature of the present invention is that malonate salts are those which impart to the composition a positive Flexibility Value of at least 1, preferably at least 1 .1 relative to water in the Porcine Skin Test." [00012]
>
> "A wide variety of counter cations to the malonate anions may be utilized in forming the salt. Malonate salts may either be the half or fully neutralized malonic acid or combinations thereof as represented by general formulas (1) and (11)" [00013]

Clearly it can been seen that the instantly claimed flexibility value of greater than 1 is not exclusively accomplished by a mixture of malonate salts since paragraph [00012] teaches malonate salts in general impart a flexibility value of 1. Further, in paragraph [00012], the appellant does not teach that the a flexibility value of 1 can only imparted by the use of a combination of malonate salt. This is evidenced by paragraph [00013] which teaches the composition may have a malonate salt *or* a combination of malonate salts. Thus, the appellant has not provided any persuasive evidence that the prior art does not have the instantly claimed flexibility value.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Sharmila S. Gollamudi

JOHANN RICHTER
SUPERVISORY PATENT EXAMINER
GROUP 1600

Conferees:

Johann Richter

Sreeni Padmanabhan

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER